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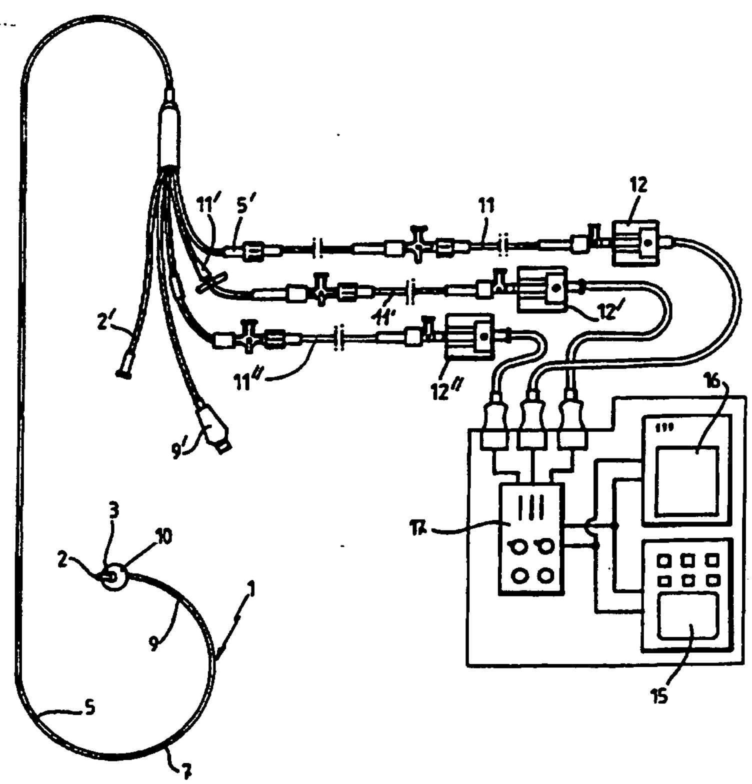
(57) Abstract

An apparatus is in development which measures the blood outflow through the heart valves by means of the bolus thermodilution method and which from then on measures the continuous cardiac output, considering the formula of Gorlin and the measurement of the blood pressure in the compartments of the heart.



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SYSTEM FOR THE MEASUREMENT OF CONTINUOUS CARDIAC OUTPUT

The invention relates to an apparatus for the continuous measurement of the cardiac output without indicator using a flow directed thermodilution catheter, consisting of :

- a distal lumen (PA) at the distal end of the catheter in order to measure the pressure in the pulmonary artery;

- a proximal lumen (RA) at about 30 cm of the distal end, in order to measure the pressure in the right atrium;

- a proximal pressure lumen (RV) at about 10 cm of the proximal lumen (RA), in order to measure the pressure in the right ventricle;

- a thermistor lumen at about 4 cm of the distal lumen;

- a balloon lumen in order to measure the wedge pressure, when the balloon is inflated;

- pressure tubing connected to the above mentioned lumina of the catheter and filled with a sterilized liquid;

- pressure transducers build as Wheatstone bridge in order to continuously measure:
  * the pressure in the right atrium RA;
  * the pressure in the right ventricle RV;
  * the pressure in the pulmonary artery;

* the wedge pressure at discrete time intervals.

The most important application of this invention will be found in Intensive Care, Operation Room, Heart catheterisation laboratories, Emergency Room and hospital units where the cardiac activity of very ill patients must be continuously followed with the help of hemodynamic monitoring.

Flow-directed catheters of the so called Swan-Ganz type are described in document EP-A-0363117. The flow directed catheter has a balloon which is inflated during the insertion of the catheter into the patient in order to lead the catheter through the heart valves into the arteria pulmonis. The balloon also makes it possible to measure the wedge pressure when inflated at the PA position, without displacement of the catheter. This type of catheter has several lumina, in order to measure the intracardiac pressures and intermittently the cardiac output by means of bolus thermodilution and in order to take bloodsamples.

This total set-up makes it possible to diagnose the patient's health condition. However measuring Cardiac Output continuously is not possible, as this measurement is restricted because of the limitation of the total amount of boluses (normal single bolus volume is 10 cc) which can be injected into the patient to measure the bolus thermodilution cardiac output.

The thermodilution cardiac output measurement is an accepted, well known technique to measure the cardiac output of a patient. To execute this technique a so called Swan-Ganz catheter is introduced into the patient in a large vein, e.g. vena jugularis, vena subcla-

via or vena femoralis. The catheter is then placed with its tip (distal end) in the pulmonary artery. Through an opening at about 30 cm of the distal end, a bolus of 10cc physiologic fluid solution of NaCl 0.9 % with a known temperature is injected into the right atrium. A temperature sensor in the pulmonary artery (approx. 26 cm distal of the injection site and about 4 cm from the distal end of the catheter) measures the temperature change and the temperature difference compared to the injected bolus temperature.

With a catheter placed in a vein or an artery the blood pressure can be measured directly. The catheter is connected to a so called pressure set, which is also filled up with fluid and which is connected to a pressure transducer. The pressure transducer is connected to an electronic device, also called hemodynamic monitor, which computes the pressure values and displays them on a screen, together with the dynamic pressure wave signal.

Also known is the measurement of contractility of the heart whereby a series of catheters of the so called Swan-Ganz type using pressure sensitive tip transducers are lead into several cavities of the heart, in order to measure various intracardial pressures. This measurement is executed in the left heart more precisely in the left atrium, the left ventricle and aorta, which gives information about overall and regional ventricle functions. Registration of the blood pressures is included in this method.

In a later stage volume-sensitive transducers have been used during the catheterisation to obtain the total pressure-volume curve. Doing so, the pressure-

volume curve is registered over one heart cycle, with the end-diastolic pressure value defined as one point within the curve.

To obtain the total curve, the measurement is repeated with several pre- and afterload conditions, e.g. by vena cava inferior clamping.

The problem however with these method is the complexity of the left heart invasive pressure measurement, which makes it useless for daily practice.

Also known is the computation of the heart preload by means of the end-diastolic pressure measurement in the left heart.

Execution of this method is obtained again by means of a Swan Ganz catheter, which is filled with fluid and which is connected to a pressure manometer resulting in the measurement of the pressure at the input of the catheter.

The method to measure the bloodflow resistance through the heartvalves is described by Kurt J. Isselbacher et al : "Harrisons' principals of internal medicine", page 985, 13th edition, 1993, Mc Graw-Hill Inc.

Using the discontinual but simultaneous measurement of blood pressure and cardiac output, one can derive the value of resistance against flow in the heart as well as in the arterial and venous blood-vessels. The area of the surface can be calculated with the formula of Gorlin :

$$A = \frac{Q}{K\sqrt{DP}\ \Delta P_{TR}}$$

with A = the surface of the valve's orifice (cm^2)
Q = the flow through the valve (ml/min)
ΔP = the mean pressure difference during the throughflow (mmHg)
K = a constant value of 44.3 for the aortic valve and a value of 37.3 for the mitralis valve.

Applied to the right heart, this formula leads to the following interpretation of Gorlin :

$$Q_H = A_{TR}K_1\sqrt{\Delta P_{TR}}$$

with Q_H = the cardiac output
A_{TR} = the real throughflow surface of the tricuspid valve, which is patient dependent
K_1 = a constant value, which is patient dependent
ΔP_{TR} = the pressure difference through the tricuspid valve between right atrium and right ventricle at the of time outflow through the tricuspid orifice (diastole of the heart cycle).

Set $A_{TR}K_1$ equal to a factor ΔP_{TR}, which we call the cardiac output-coefficient of the individual, then the formula of Gorlin is replaced by :

$$Q_H = Q_{I,TR}\sqrt{\Delta P_{TR}} \qquad [6]$$

with Q_H, $Q_{I,TR}$ en ΔP_{TR} as described before.

The invention assumes that once the resistance against flow has been defined, it will stay stable over a longer time, under certain conditions, and therefore can be used as a calibration parameter for the continuous cardiac output measurement based on the measurement of pressure difference between the compartments of the heart.

To measure the compartment pressures and to calculate the continuous cardiac output, this invention suggests an apparatus which is described under conclusion 1 and which measures the hemodynamic parameters and computes the continuous cardiac output, as follows :

- the pressure difference ΔP_{TR} between right atrium and right ventricle at the time of outflow through the tricuspid orifice (diastole of the heart cycle);

- the cardiac output by means of the bolus thermodilution, in order to calibrate the system.

In other words, ones $Q_{I,TR}$ has been calculated, it suffices to measure in a continuous way the value of ΔP_{TR} to derive the continuous cardiac output Q_H.

These characteristics and other characteristics of the invention will further on been described, with reference to the figures in addition, which are added as an example and do not restrict the work out of the invention.

In these drawings :

- **figure 1** shows a practical lay-out of the apparatus for the continuous cardiac output, by means of the invention;

- **figure 2** shows a heart section with indication of the locations of the catheter and the different lumina;

- **figure 3** is a printout of some pressure signals;

- **figure 4** is a display lay-out of the apparatus.

In these figures, the same reference signs are used for corresponding elements.

As shown in figures 1 and 2, an apparatus for the measurement of continuous cardiac output with the help of the catheter with flow-directed catheter 1 consists of :

- a distal pressure lumen 2 located at the distal end 3 of catheter 1 and which measures the pressure of the arteria pulmonalis 4;

- a proximal pressure lumen 5 located at about 30 cm of the distal end 3 and measures the pressure of the right atrium 6;

- a proximal perfusion lumen 7 located at about 10 cm of the proximal opening and which measures the pressure of the right ventricle 8;

- a thermistor lumen 9 located in the arteria pulmonalis at about 4 cm of the distal opening 2;

- a balloon lumen 10 in order to measure the wedge pressure by means of lumen 2, when the balloon is inflated, through lumen 10';

- pressure tubing lines 11, 11', 11" connected to lumen 5', 7' and 2' of catheter 1 and which are filled with sterilisated fluid;

- pressure transducers 12, 12', 12" measuring the pressure based on the Wheatstone bridge principals;

- the pressure in the right atrium 6;

- the pressure in the right ventricle 8;

- the pressure in the pulmonary artery 4 and the wedge pressure at discrete time intervals, at the moment the balloon is inflated.

The calculation of $Q_{I,TR}$ is executed as follows :

During the diastolic period of the heartcycle, the bolus thermodilution cardiac output CO_t value is measured simultaneously with the pressure difference ΔP_{TR} between right atrium 6 and right ventricle 8 by means of the same catheter 1.

The obtained cardiac output by thermodilution (CO_t) is the typical cardiac output for the individual at time t, and is set to $CO_{I,t}$.

The cardiac output of the right atrium is the amount of blood per time unit, which flows through the tricuspid valve. This amount can increase to 5 times the normal value in man.

Considering formula (6) we obtain :

$$CO_{I,t} = Q_{ITR,t} \quad \sqrt{\Delta P_{TR,t}}$$

and in other words $Q_{ITR,t} = \dfrac{CO_{I,t}}{\sqrt{\Delta P_{TR,t}}}$ [7]

This measurement will be repeated N times, by preference 5 times, out of which the mean value of the thermodilution cardiac output Q_{ITR} is derived as :

$$Q_{ITR} = \frac{\Sigma^{N}_{t=1} \quad Q_{ITR,t}}{N} \qquad [8]$$

Q_{ITR} being calculated it is sufficient to measure DPTR in a continuous matter, as the pressure difference between right atrium 6 and right ventricle 8, in order to calculate in a continuous matter the continuous cardiac output Q_H considering (6), i.e. :

$$Q_H = Q_{ITR}\sqrt{\Delta P_{TR}} \qquad [9]$$

It should be noticed that ΔP_{TR} has to be considered as the pressure difference during outflow through the right atrium by means of an haemodynamic monitor, which means during the period in which the right atrium pressure is greater than the right ventricle pressure. Two periods can be recognised, i.e. the active and the passive outflow period.

In the same way, it is possible to calculate the continuous cardiac output QH at the pulmonary artery valve by means of the pressure difference ΔP_{PA} over the pulmonary artery valve, which is the pressure difference between right ventricle and pulmonary artery during the period of outflow through the pulmonary artery valve. The following formules are valid :

[6] becomes $Q_H = Q_{IPA}\sqrt{\Delta P_{PA}}$ [6']

with Q_H = the cardiac output;
Q_{IPA} = the cardiac output coefficient of the individual at the pulmonary artery valve;
ΔP_{PA} = the pressure difference over the pulmonary artery valve, which is the pressure difference between right ventricle and pulmonary artery during the outflow through the pulmonary artery valve. This outflow period is the systolic period of the heartcycle.

[7] becomes $Q_{IPA,t} = \dfrac{CO_{I,t}}{\sqrt{\Delta P_{PA,t}}}$ [7']

[8] becomes $Q_{IPA} = \Sigma^{N}_{t=1} \dfrac{Q_{IPA,t}}{N}$ [8']

[9] becomes $Q_H = Q_{IPA} \sqrt{\Delta P_{PA}}$ [9']

with $\Delta P_{PA} = \int^{T5} \Delta p_{PA} dt + \int^{T7} \Delta p_{pa} dt$

As the calculations over the tricuspid valve and the pulmonary artery valve relate to the cardiac output, it will be possible to obtain also other parameters considering the equality of formula (9) and (9').

Such parameters can be the ejection fraction, the compliance, the afterload information, valve delays but also higher accuracy of the cardiac output value.

It has to be considered also that the blood velocity value, particulary when derived from the blood pressure, will help to optimise the obtained continuous cardiac output value.

C L A I M S

1. System for the measurement of continuous cardiac output consisting of :

- a distal pressure lumen (2) located at the distal end (3) of catheter (1) and which measures the arteria pulmonalis (4);

- A proximal pressure lumen (5) located at about 30 cm of the distal end (3) and measures the pressure of the right atrium (6);

- a proximal pressure lumen (7) located at about 10 cm of the proximal opening and measures the pressure of the right ventricle (8);

- a thermistor lumen (9) located in the arteria pulmonalis at about 4 cm of the distal opening (2);

- a balloon lumen (10) in order to measure the wedge pressure by means of lumen (2), when the balloon is inflated, through lumen 10';

- pressure tubing lines (11, 11', 11") connected to lumina of the catheter and which are filled with sterilized liquid;

- pressure transducers (12, 12', 12") measuring the pressure based on the Wheatstone bridge principles;

- the pressure in the tight atrium (6);

- the pressure in the right ventricle (8);

- the pressure in the pulmonary artery 4 and the wedge pressure at discrete time intervals, at the moment the balloon is inflated;

and which monitors hemodynamic signals (16) and contains an algorithm which calculates :

- the pressure difference over the tricuspid valve (17) as the pressure difference between right atrium (6) and right ventricle (8) during the out-flow or diastolic period;

- the pressure difference over the pulmonary artery valve (18) as the pressure difference between right ventricle (8) and pulmonary artery (4) during the out-flow or systolic period;

- the cardiac output in a non-continuous manner by means of thermodilution cardiac output;

- and with this values the continuous cardiac output.

2. Apparatus as described under conclusion 1, with the special feature that it has a catheter which is connected to a so called pressureline. Catheter and pressureline are filled with a sterilised fluid. The pressureline is connected to a pressure transducer and a device which calculates the blood pressure and also displays the pressure signal.

3. Apparatus as described under conclusion 1 and 2, with the special feature that it calculates at all

times the pressure difference between right atrium 6 (RA) and right ventricle 8 (RV) and the pressure difference between right ventricle 8 (RV) and pulmonary artery 4 (PA) and which computes the integral value of this pressure difference curves over a defined time period.

FIG. 1

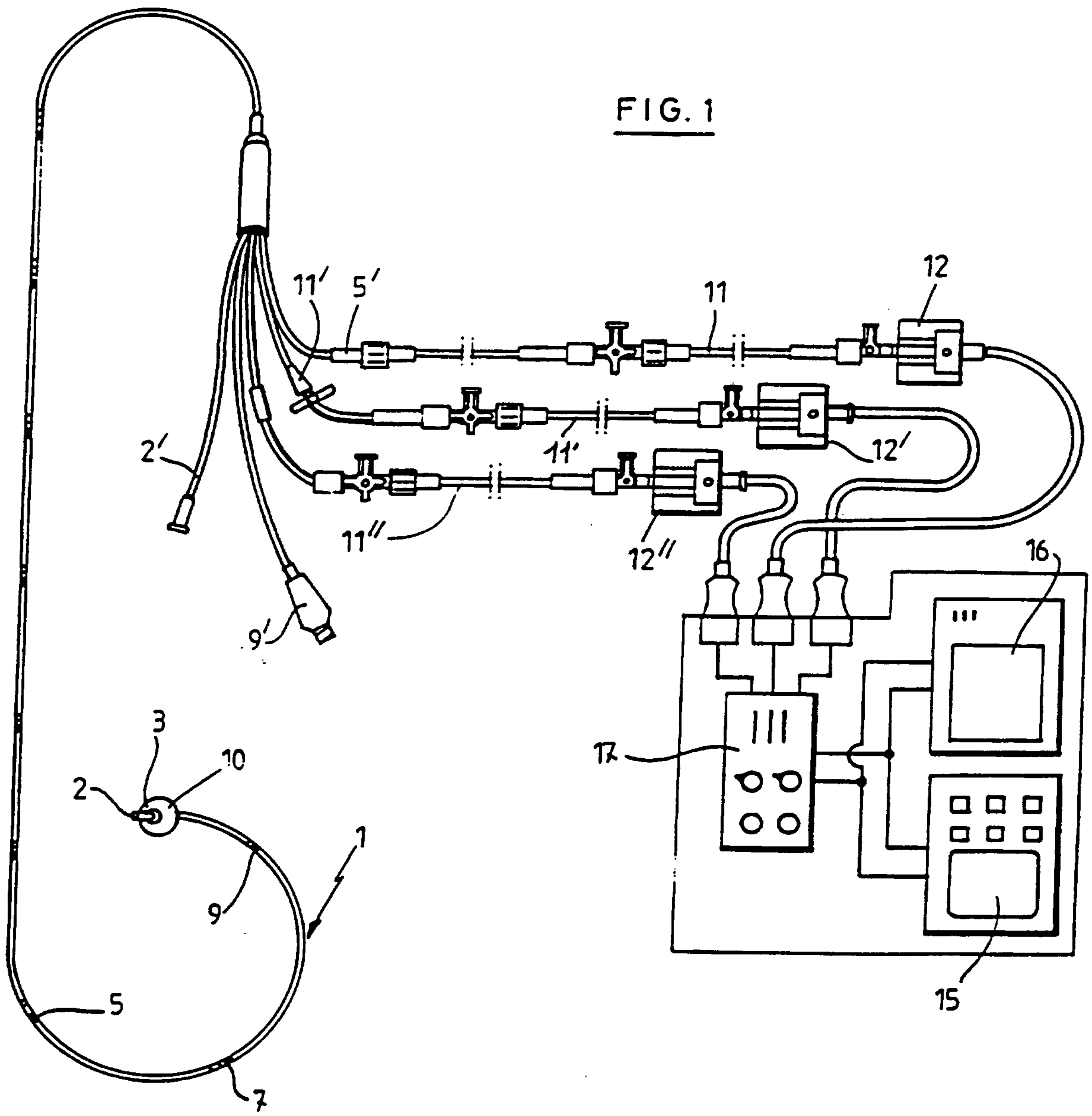


FIG. 2

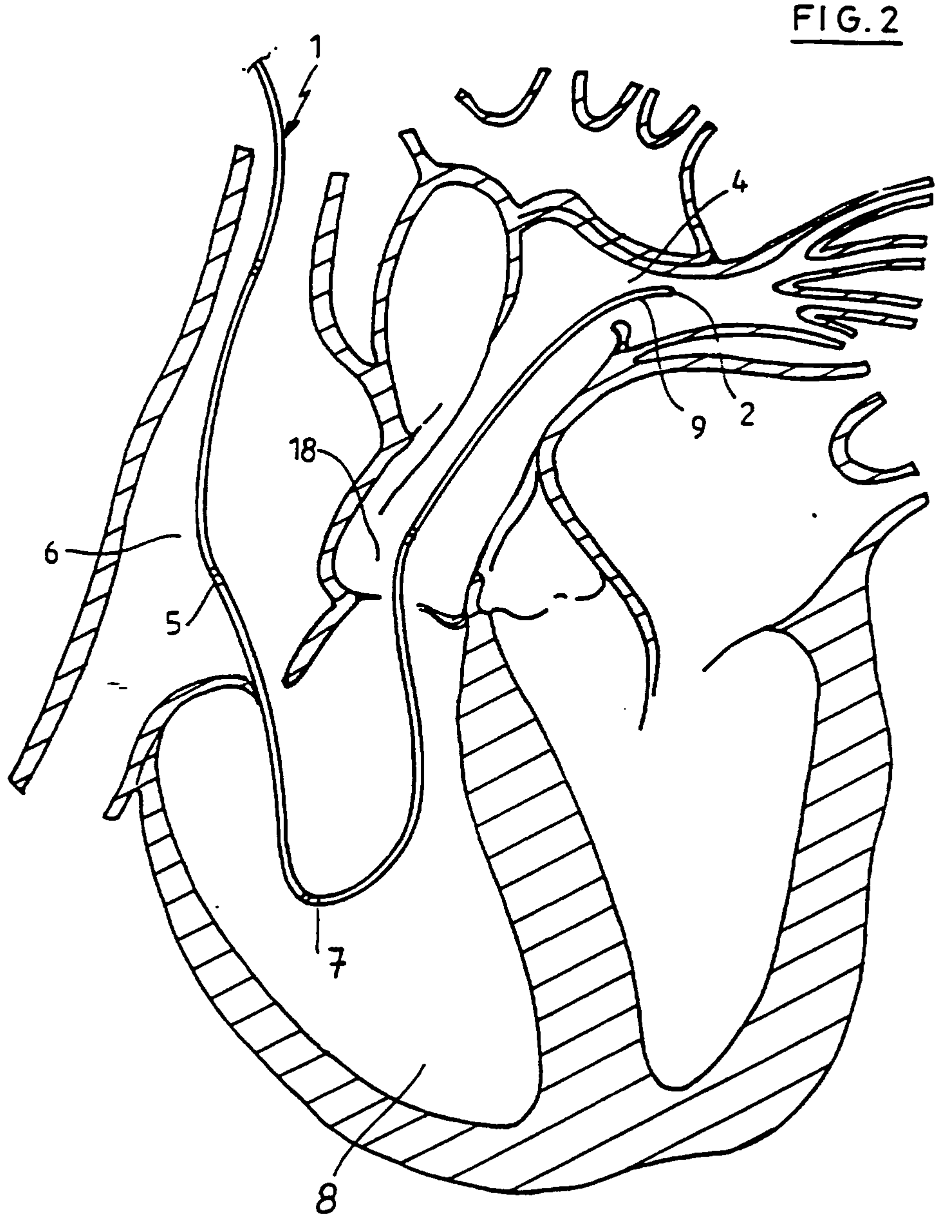


FIG. 3A

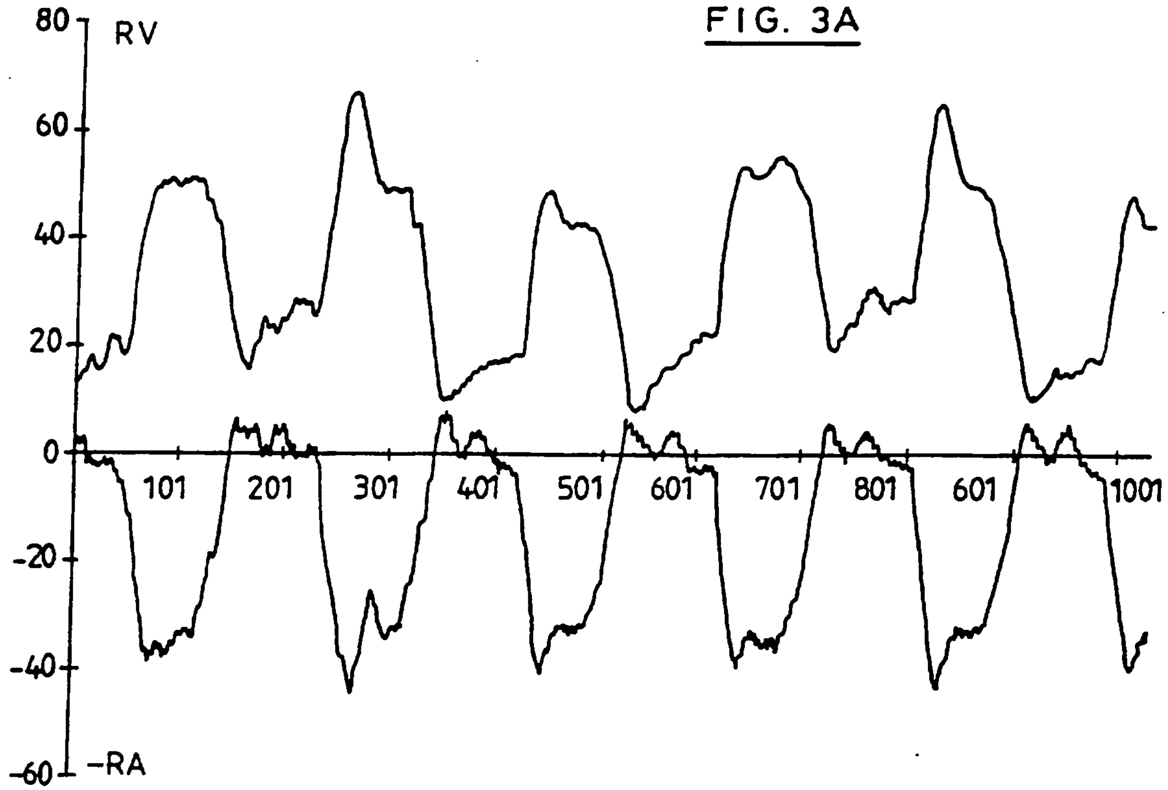
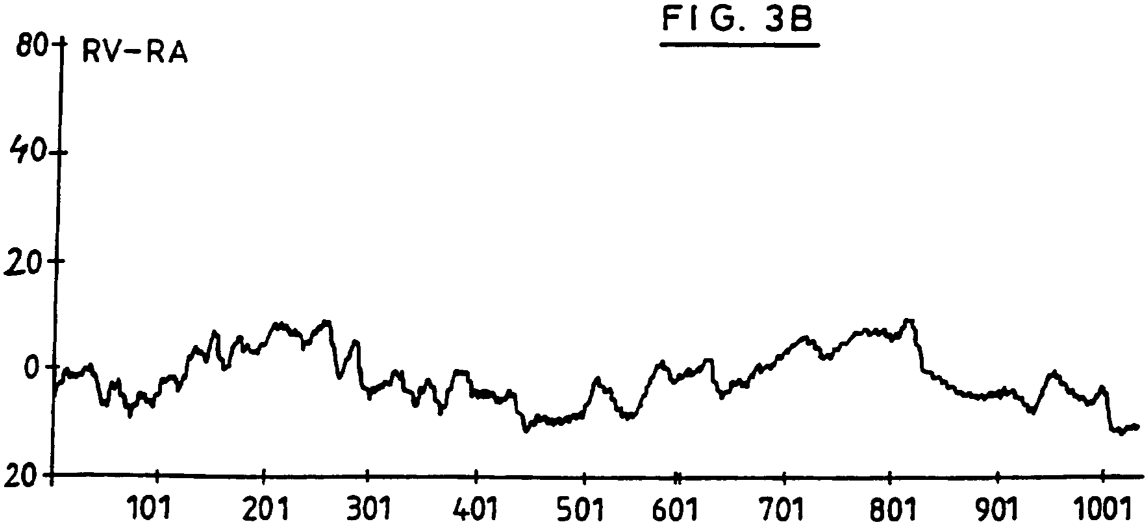

80
60
40
20
0
-20
-40
-60
RV
-RA
101
201
301
401
501
601
701
801
601
1001

FIG. 3B


80
40
20
0
-20
RV-RA
101
201
301
401
501
601
701
801
901
1001

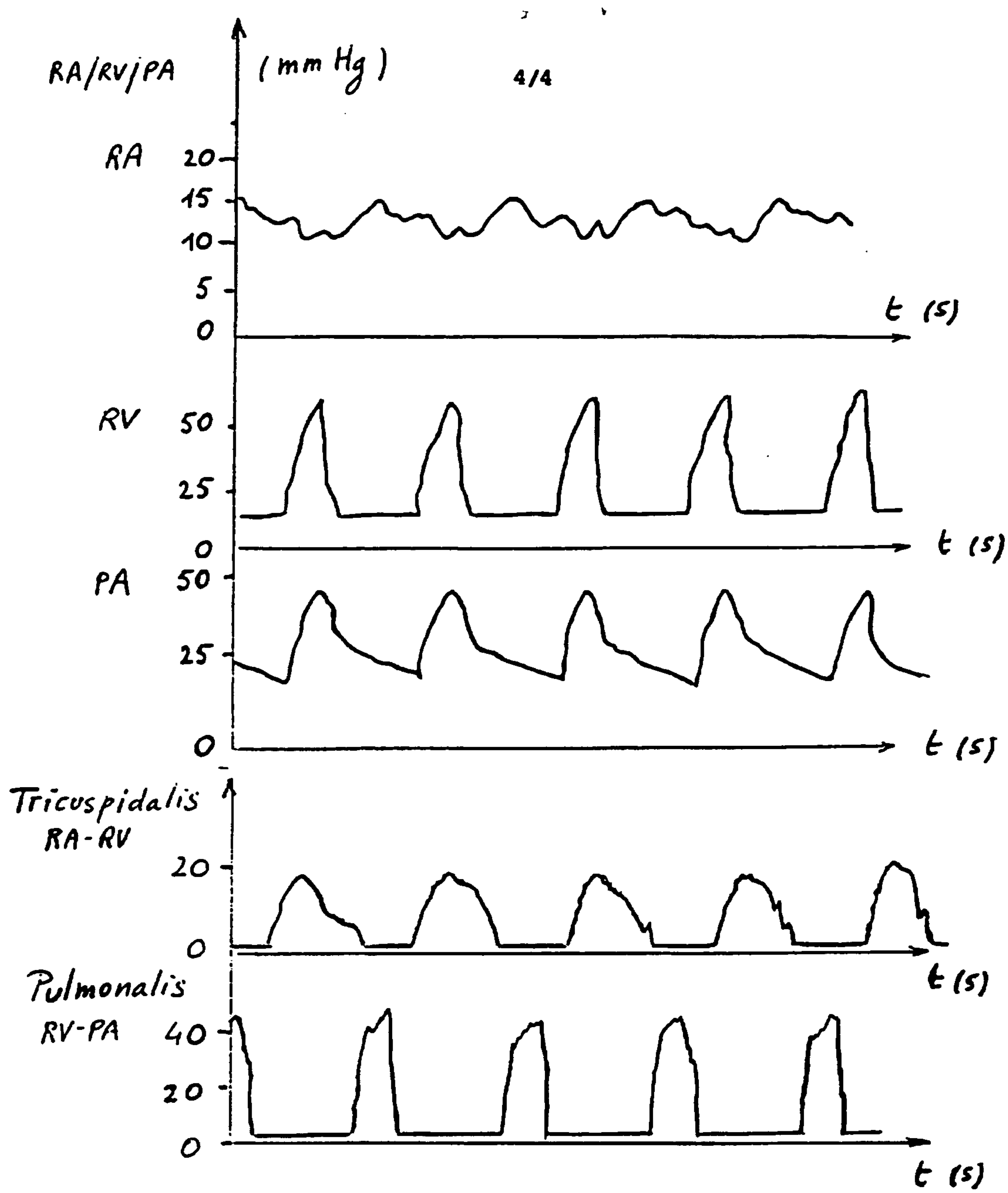

RA/RV/PA
(mm Hg)
RA
20
15
10
5
0
t (s)
RV
50
25
0
t (s)
PA
50
25
0
t (s)
Tricuspidalis
RA-RV
20
0
t (s)
Pulmonalis
RV-PA
40
20
0
t (s)

FIG. 4